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Jay Prabhakar Gore

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EXAMINER

GAKH, YELENA G

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

07/07/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/692,996	Applicant(s) GORE ET AL.	
	Examiner Yelena G. Gakh, Ph.D.	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11, 16-23 and 25-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11, 16-23 and 25-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed on 04/24/09 is acknowledged. Claims 1-5, 11, 16-23 and 25-69 are pending in the application.

The Terminal Disclaimer filed on 04/29/09 is disapproved.

Response to Amendment

2. In response to the amendment and the Applicants' remarks the examiner withdraws objection to introducing the new matter and modifies rejections under 112, first and second paragraphs and over the prior art.

Examiner's Note: claims 19 and 21 recite a mean-centered integrated absorbance ratio, while claims 20 and 22 recite mean-centered integrated absorbance. Therefore, it would be logical to recite claims 19 and 21, as well as claims 20 and 22 sequentially. The examiner suggests exchanging the claim numbers 20 and 21.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 11, 16-23 and 25-69 of the instant application are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 7,288,768 in view of Krueger et al. (US 5,365,066) (Krueger), as evidenced by Kim et al. (IEEE Photonics Technology Letters, 2000) (Kim). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recite essentially the same subject matter for the method of detecting an organic compound, in particular glucose in the instant application and fat in the patent, using IR spectroscopy with converting optical signals from several absorption ranges into electrical signals with the following processing of the signals using a multivariant calibration algorithm. The only difference between the pending claims and those of the issue patent is the step of transmitting incoherent IR radiation. However, transmitting incoherent radiation is well known in the art, as can be seen from e.g. US 5,365,066, which discloses "LED/IRED near-infrared instruments having improved measurement sensitivity" for measuring glucose (col. 1, lines 23-25), with LED being well known sources of incoherent radiation (see Kim, page 921, left column).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 11, 16-17, 19-23 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite a method of measuring *an amount of organic substance* contained within a biological sample, while the whole disclosure is directed

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toward the method of detecting *glucose* level in the biological sample, with no other organic compounds disclosed in the specification as being measured by the claimed method.

The examiner respectfully reminds the Applicants that according to MPEP §2163:

"2163.02. Standard for Determining Compliance with Written Description Requirement:

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

The Applicants did not reasonably convey to a skilled in the art that they possessed the invention in the full scope of the claims at the time when the application was filed by "describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention".

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-5, 11, 16-23 and 25-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "transmitting incoherent infrared radiation". However, it is not clear, as to what the Applicants mean by the term "incoherent". By definition, incoherent radiation - the radiation, which does not have properties of the coherent radiation, with the coherent radiation being "the radiation emitted by a source when all the elementary waves emitted have a phase difference constant in space and time" (see definitions in IUPAC Compendium of Chemical Terminology, 1997). The examiner did not find any indication in the instant disclosure which would indicate the sources of incoherent radiation. Instead, in paragraph [0071] of the pre-publication of the instant application, US 2004/0147034 the definition is the following: "[w]ith respect to coherent or incoherent infrared electromagnetic radiation, it should be understood that, as discussed in greater detail below, an organic substance has an infrared absorption spectrum which includes a set (n) of wavelength regions with each wavelength region corresponding to an absorption band of the absorption spectrum". The examiner failed to find anywhere either referring to the source of incoherent radiation, or indication, as to how the incoherent radiation is obtained. It makes it unclear, as to what the Applicants mean by the term "incoherent" in the instant case, since no incoherence of the phase of the emitted IR radiation is mentioned anywhere in the specification.

Claim 28 recites "the infrared detector measures the intensity of radiation at less than 10 discrete wavelength bands". This expression is not definite, since there is a plurality of ways the infrared detector can measure the intensity of radiation at discrete wavelengths including post-detected processing of the signal, which would still be considered "measuring of the intensity of radiation". Since claim 28 does not specifically recite any spectral filtering of the signals transmitted by the sample, the examiner interprets them in the broadest sense, i.e. as any operation that allows measuring discrete wavelengths bands.

In claim 57 the limitation "the modulated mid infrared radiation" in step (4) does not have an antecedent basis.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claims 1-5, 11, 16-23 and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lillenfild-Toal (US 6,484,044) in view of Krueger et al. (US 5,365,066) (Krueger), as evidenced by Kim et al. (IEEE Photonics Technology Letters, 2000) (Kim).

Lillenfild-Toal teaches a method of measuring an amount of an organic substance (glucose) (*claim 2*) contained within a biological sample, the compound having an infrared absorption spectrum, which includes a set of wavelength regions (see Figure 3), the method comprising detecting a number of selected wavelength bands from the spectrum less than the total number of the wavebands of the compound: for example detecting at least three different wavelengths (col. 4, lines 1-2) of selected wavenumbers 1151, 1105, 1080, 1036 and 992 cm^{-1} (col. 4, line 15) (corresponding to detecting in the regions recited in *claims 6-8 and 14-16*); generating an electrical signal in photoacoustic sensor (in piezoelectric transducer 6, col. 3, lines 44-45) in response to detecting the intensity of the bands at these wavenumbers; and processing said electrical signal with a quantification algorithm, e.g. "by a least square calculation referring to reference spectra such as shown in FIGS. 2 or 3 for known glucose concentrations. The calculated concentration is displayed on display 9. Alternatively, the glucose concentration could also be calculated from an average of concentrations obtained from the absorptions at each wavelength relative to reference absorption for a reference glucose concentration determined beforehand" (col. 4, lines 26-34) (*claims 1 and 3-5*). Equations recited in *claims 19-22* are conventional equations for partial least square analysis with the number of contributions defined by the number of input wavelengths.

Lillenfild-Toal does not specifically disclose transmitting incoherent IR radiation.

However, transmitting incoherent radiation for measuring glucose is well known in the art, as can be seen from e.g. US 5,365,066, which discloses "LED/IRED near-infrared instruments having improved measurement sensitivity" for measuring glucose (col. 1, lines 23-25), with LED being well known sources of incoherent radiation (see Kim, page 921, left column).

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It would have been obvious for a person of ordinary skill in the art to modify Lillenfeld-Toal's method by utilizing incoherent radiation for measuring glucose, as disclosed by e.g. Krueger, as evidenced by Kim, since it improves measurement sensitivity.

8. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over anyone of Heise et al. (Appl. Spectr., 1994) (Heise), Bhandare et al. (Appl. Spectr., 1994) (Bhandare), Budinova et al. (Appl. Spectr., 1997) (Budinova), or Vonach et al. (Appl. Spectr., 1998) (Vonach) in view of Sterling et al. (US 6,025,597, IDS) (Sterling).

All references disclose a method of measuring a glucose level within a biological sample using mid-infrared spectroscopy by measuring a set of wavelength regions, in which glucose absorbs in mid-IR range: $1200\text{-}950\text{ cm}^{-1}$ (see e.g. Heise, page 88, left column) by obtaining a sample of a biological fluid, passing an incident signal of indicated wavelength through the sample, detecting a post-absorbance signals and calculating glucose concentration from said post-absorbance signal. All references disclose detecting glucose at specific wavelengths: "for glucose, the best predicting results were achieved within the rather narrow spectral range of 1200 to 950 cm^{-1} , where the most intensive absorption bands of aqueous glucose exist" (Heise, page 88, left column); Budínova discloses the following wave-numbers for glucose, which slightly differ from the ones recited in the claims: 1035 , 1078 , 1104 and 1148 cm^{-1} with the full range of $1185\text{-}950\text{ cm}^{-1}$; Vonach indicates that "the spectral change [upon adding glucose] is in accordance with the glucose absorption with its maxima at 1038 and 1080 cm^{-1} " (page 821, left column).

Heise, Bhandare, Cadet, Budínova or Vonach do not specifically disclose using spectral filtering for discrete detecting the signals at discrete wavelength bands of glucose.

Sterling discloses a wavelength selection system for selecting specific wavelengths of IR spectra, specifically discrete infrared bandpass filters (col. 10, lines 46), indicating the following:

"The use of a specific set of bandpass filters restricts the instrument to analyzing only pre selected wavelengths. The use of the FTIR allows the optical measurements of all wavelengths. When using an FTIR the final analysis wavelengths are selected in the signal processing computer. Therefore an instrument built with discrete filters is dedicated to measuring a predetermined compound, e.g. glucose, while an instrument built using an FTIR can be directed via software modifications to measure any of a number of compounds such as glucose, alcohol, etc." (col. 10, lines 57-67).

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Thus, Sterling provides direct disclosure for both types of methods, i.e. the method of using FTIR instrument with post-detected processing the signals related to the analyte, e.g. glucose, or method of using spectral filters build-in into the IR spectrometer for the specific analyte, e.g. glucose, which makes the modification of any of the teachings provided above for FTIR analysis of glucose obvious for a person of ordinary skill in the art.

9. **Claim 27** is rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (US 5,054,487) in view of e.g. Müller (US 4,427,889).

Clarke discloses the following:

Systems and methods for material analysis are disclosed in which a material (e.g., **a liquid such as blood**) is illuminated **at a plurality of discrete wavelengths**. Measurements of the intensity of reflected light at such wavelengths are taken, and an analysis of reflection ratios for various wavelengths is performed. Changes in the reflection ratios can be correlated with specific material properties such as the concentration of analytes (e.g., oxygen content, **glucose levels**, cholesterol or drugs in a subject's circulatory system). In one aspect of the invention, an analytic apparatus and method are described employing a multi-wavelength illumination source, a wavelength specific detector array, and a reflection ratio analyzer. **The illumination source illuminates a material sample at a plurality of discrete wavelengths. The detector array detects the light reflected from the sample, converts the detected light into electrical signals indicative of the intensity of the reflected light at each wavelength, and transmits the converted signals to a reflection ratio analyzer.** The reflection ratio analyzer then derives a reflectance ratio for at least two of the detected wavelengths, such that the ratio can be compared with predetermined values to detect the presence and/or concentration of an analyte in a material sample. *Although the illustrated embodiment shows a system with a fiber optic bundle for delivery of six distinct wavelengths of light, it should be clear that the number of interrogation wavelengths, the size and shape of the sampling head and the means for transmitting the light to and from the sample can be varied to meet particular needs and applications. In particular, a single fiber can be used for transmission and detection of multiple interrogation wavelengths. Moreover, although lasers are described as preferred light sources, other illumination means including non-coherent, discrete wavelength light sources can be employed.*" (Col. 1, lines 59-69 and col. 2, lines 1-16).

While Clarke does not specifically teach irradiating the sample with the discrete wavelengths corresponding to the absorption spectrum of the organic compound, it would have been obvious for a person of ordinary skill in the art to modify Clarke's method by narrowing down selected discrete wavelengths in order to irradiate the sample with the wavelengths closest to absorption signals of the organic compound under analysis in order to exclude the spectral lines of interfering compounds, and in order to determine the reflection ratio in a more precise

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way. Calibrating a detection system with a set of reference samples is a totally conventional and routine step in performing measurements with IR spectrometer.

While Clarke does not specifically teach using mid-IR range for measuring glucose, this range is well known in the art, as indicated by e.g. Müller, who discloses measuring glucose with mid-IR radiation, see Figures 1-5, which makes it obvious for a person of ordinary skill in the art to use mid-IR range utilized by Müller in Clarke's method.

10. **Claims 28-51 and 56** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lillenfeld-Toal in view of Krueger, as evidenced by Kim, and Purdy et al. (US 5,460,177) (Purdy).

Disclosure of Lillenfeld-Toal in view of Krueger, as evidenced by Kim can be read in paragraph 7 of the present Office action.

Lillenfeld-Toal/Krueger do not specifically teach modulation of infrared radiation.

However, overheating the biological sample with intensive NIR or mid-IR radiation is a problem in analysis of component of biological sample, as discussed by Purdy.

Purdy indicates: “[c]ontinuous-spectrum noninvasive techniques make use of radiation in the near-infrared portion of the spectrum. However, in this portion of the spectrum, the absorption of radiation by water is very high. In addition, the concentrations of the analyte of interest in the bloodstream is typically low. As a result, the contribution of the analyte of interest to the signal intensity is only a relatively small change in the total signal intensity obtained by this technique. It has been found that detector noise is of the same order of magnitude as the change in intensity signal resulting from variations in analyte concentration. The variations in signal intensity as a result of variations in concentration of the analyte of interest are so small that, at intensities that have been used in the past, the detector's sensitivity may not be high enough to obtain sufficiently accurate readings. A possible solution to this problem would be to increase the intensity of the radiation incident on the body part of the subject. However, an increase in the intensity of incident radiation increases the amount of energy absorbed by the body part. Increases in the energy absorbed by the body part result in greater heating of the body part the amount of heat produced. Excessive heating can cause discomfort and even burns to the subject, which obviously would be undesirable. It is accordingly an object of this invention to provide a method for the continuous spectrum non-invasive spectroscopic detection of analytes

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in the bloodstream of living animals with increased signal-to-noise ratio” (col. 1, lines 64-67 and col. 2, lines 1-25).

Purdy provides a solution to the problem by using a chopper for periodically interrupting radiation emitted from the bulb, i.e. modulating intensity of the incident signal: “A method for non-invasive detection of the concentration of an analyte in the blood of a living animal includes the steps of irradiating a body part of the animal with intensity-modulated radiation over a continuous spectrum; detecting the intensity of radiation emitted from the body part at a plurality of discrete wavelength ranges within the continuous spectrum; and using the detected intensity to calculate the concentration of the blood analyte” (col. 2, lines 31-39) The chopper by definition is a device which periodically blocks the infrared radiation, and therefore can have any structure comprising IR transparent and non-transparent parts.

It would have been obvious for any person of ordinary skill in the art to modulate intensity of the incident signal as taught by Purdy in Lillenfild-Toal/Krueger’s methods for the reasons analogous to the ones indicated by Purdy, i.e. in order to prevent overheating of the sensitive biological sample, because the analysis is performed by using radiation in thermal range (mid-IR frequencies).

Since the measurement path is defined by penetration of the mid-IR incident radiation and therefore defined the output data, it would have been obvious for any person of ordinary skill in the art to optimize the penetration depth (measurement path) in order to obtain the most accurate results by comparing with the reference data.

11. **Claims 52-55** are rejected under 35 U.S.C. 103(a) as being unpatentable Lillenfild-Toal in view of in view of Krueger, as evidenced by Kim, and Purdy, as applied to claims 28-51 and 56 above, and further in view of Rule et al. (US 2003/0040683 A1) (Rule).

Lillenfild-Toal in view of Krueger and Purdy do not specifically disclose the second modulation technique, which comprises e.g. modulating of laser emitted signal with a specific frequency, such as in the range of 0.1 Hz-10 Hz, specifically 3 Hz.

Rule discloses "site selection for determining analyte concentration in living tissue" (Title) with the analyte being glucose and the analytical method - IR spectroscopy. In particular, Rule teaches: "[0152] The radiation emitted from the source 220 is in one embodiment modulated at a frequency between about one-half hertz and about one hundred hertz, in another

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embodiment between about 2.5 hertz and about 7.5 hertz, in still another embodiment at about 50 hertz, and in yet another embodiment at about 5 hertz. With a modulated radiation source, ambient light sources, such as a flickering fluorescent lamp, can be more easily identified and rejected when analyzing the radiation incident on the detector 250".

It would have been obvious for a person of ordinary skill in the art to further modify the method of Lillenfild-Toal/Krueger-Purdy by applying the second modulation technique, such as the one disclosed by Rule, i.e. modulating radiation emitted by the IR source with the frequency within 0.1Hz-10 Hz range, because of the same reasons as indicated by Rule, e.g. in order to identify interfering radiation sources and correct for possible errors. It would have been obvious for a person of ordinary skill in the art to optimize the frequency of modulation within this range, and choose the frequency of 3 Hz for specific IR sources.

It would have been obvious for a person of ordinary skill in the art to substitute IR chopper, which blocks IR radiation, with the IR absorbing material, because it gives the same effect of preventing IR radiation from reaching the sample, and thus prevents overheating the sample.

12. **Claims 57-69** are rejected under 35 U.S.C. 103(a) as being unpatentable Lillenfild-Toal in view of Krueger and Purdy and Sterling et al. (US 6,025,597, IDS) (Sterling).

Combined teaching of Lillenfild-Toal in view of Krueger and Purdy can be read in paragraph 10 of the present Office action.

Lillenfild-Toal/ Krueger -Purdy do not specifically disclose using spectral filtering for discrete detecting the signals at discrete wavelength bands of glucose.

Sterling discloses a wavelength selection system for selecting specific wavelengths of IR spectra, specifically discrete infrared bandpass filters (col. 10, lines 46), indicating the following:

"The use of a specific set of bandpass filters restricts the instrument to analyzing only pre-selected wavelengths. The use of the FTIR allows the optical measurements of all wavelengths. When using an FTIR the final analysis wavelengths are selected in the signal processing computer. Therefore an instrument built with discrete filters is dedicated to measuring a predetermined compound, e.g. glucose, while an instrument built using an FTIR can be directed via software modifications to measure any of a number of compounds such as glucose, alcohol, etc." (col. 10, lines 57-67).

Thus, Sterling provides direct disclosure for both types of methods, i.e. the method of using FTIR instrument with post-detected processing the signals related to the analyte, e.g.

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glucose, or method of using spectral filters build-in into the IR spectrometer for the specific analyte, e.g. glucose, which makes the modification of Lillenfild-Toal/ Krueger -Purdy' method in light of Sterling obvious for a person of ordinary skill in the art.

All filtration methods for the biological samples, specifically blood, recited in the dependent claims, are conventional for preparation of the sample for IR analysis, and therefore are obvious for a person of ordinary skill in the art.

Response to Arguments

13. Applicant's arguments filed 04/24/09 have been fully considered but they are not persuasive.

Specification: the specification was objected under 35 U.S.C. 132(a) because the amendment introduced new matter into the disclosure. The objection is withdrawn.

The Terminal Disclaimer was not approved and thus ODP rejection is maintained.

Rejection of the pending claims under 35 U.S.C. 112, first paragraph. After the rejection was overcome by the amendment, a new issue was raised regarding insufficient disclosure for the scope of the claims.

Rejection of the pending claims under 35 U.S.C. 112, second paragraph. Regarding claims 19-22, the Applicants are correct in that these claims were not supposed to be rejected under 35 U.S.C. 112, second paragraph. In fact, the examiner suggested interchanging the claim numbers 20 and 21, so that the subject matter of claims 19 and 20 and 21 and 22 would be recited in a more logical way.

Regarding rejection of the pending claimed under 35 U.S.C. 103(a).

Applicants' arguments regarding rejection of claims 1-5, 11, 16-23, 25 and 28-69 over the prior art are moot in view of the new grounds for rejections. However, the examiner would like to note that the following Applicants' statement: "[t]he Examiner correctly has concluded that Lillenfild-Toal does not teach **transmitting infrared radiation**; therefore, it necessarily follows that Lillenfild-Toal does not teach **detecting the transmitted radiation**", is in fact incorrect. The examiner did not indicate that Lillenfild-Toal does not teach transmitting infrared radiation - what else can Lillenfild-Toal teach, if he teaches detection of glucose with IR spectroscopy? The examiner indicated that Lillenfild-Toal does not teach transmitting **incoherent** IR radiation.

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Regarding rejection of claim 26, it is not apparent, as to what the mathematical transformation of the signals, specifically Fourier-transform, has to do with transmitting infrared radiation? The examiner did not find anywhere in the claim recitation of the "simple transmittance experiments". Furthermore, Budinova recites the "simple transmittance experiments" in association with attenuated total reflectance (ATR), which is also not recited in claim 26. Moreover, it is not apparent, as to why the Applicants constantly refer to the mid-IR spectrum, which is difficult to measure with FTIR, when no mid-IR is recited in the claim? This renders the Applicants' arguments irrelevant to the recited subject matter and to the rejections established by the examiner.

The Applicants further question the examiner's application of the references teaching FTIR to the claim, which does not comprise FTIR. To the examiner's understanding, the claim is recited as an open-ended claim, which can comprise FTIR transformation of the transmitted radiation, with transmitted radiation being detected through Fourier transformed signal. The examiner would like to provide a reference of Ng et al. (IEEE, 2007 9th Electronics Packaging Technology Conference), which specifically defines the terminology:

"3.0 Results and Discussion

3.1 Fingerprint Identification

Infrared radiation is generally consists of three regions, namely the Near-infrared, Mid-infrared and Far-infrared. The measurement units are frequency (Hz), wavenumber (cm⁻¹) or wavelength (μm). The FTIR spectra collected from this study is referring to the Mid-infrared region, by which the most widely used region of molecular vibration typically applied in the organic molecular structure. When infrared radiation is directly onto a surface, it will be either ***transmitted/absorbed*** or reflected by the sample's surface. ***In this study, the FTIR Spectrum One detector measures the transmitted mid-infrared radiation.*** The instrument's spectrometer collects the percentage radiation transmission measurement of the sample's surface, or the absorbance value through electronic transformation. ***This is generally termed as the Transmittance and Absorption mode of FTIR spectra. Transmittance mode scale is usually used for interpretation of spectra;*** and the Absorbance scale is applied for quantitative work data analysis. The relationship between the Transmittance and the Absorbance are commonly being expressed by the below equation.

$$A = \text{Log}_{10} [I_0 / I]$$

whereby,

A = Absorbed radiation

I₀ = Total incident radiation

I = Transmitted radiation". (Page 653, right column).

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The Applicants' arguments regarding Sterling reference are not clear to the examiner. The examiner does not use Sterling as teaching transmittance technique, but rather as teaching the way of transforming the signals by either using FTIR technique or filters. It is not essential, whether the signals are reflectance or transmittance signals. The same technique can be applied to both types of signals. Sterling specifically indicates that both types, FTIR and filtering, are possible in signal detection, which is perfectly applicable to the transmittance mode recited in the primary references, indicated by the examiner. Thus, the Applicants arguments regarding claim 26 are not convincing.

Regarding rejection of claim 27, the examiner is not quite sure, as to whether the Applicants state that calibration of an IR spectrometer with a set of reference samples is a novel feature of the claimed method. To the examiner's knowledge, this is not only a conventional and routine procedure, but is in fact a requirement for most IR spectrometers. As to the limitation of illuminating the biological sample with mid-infrared radiation, this is a new limitation in the claim, and therefore the examiner does not believe that it was possible to address this limitation in the previous Office action. The limitation is addressed in the present Office action. As to the filtering, the examiner specifically indicated, why it would have been obvious for a person of ordinary skill in the art to use filtering of specific IR bands in Clarke's method. The examiner would like to remind the Applicants that Clarke was not used as an anticipatory reference, and therefore modification of Clarke's teaching is assumed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Y. Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

7/1/2009